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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,790	01/14/2002	Richard A. Rosenbloom	QUIG-1006CIP	3053

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/045,790	ROSENBLOOM, RICHARD A.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-20 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, 9-20, 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/17/2006. Claim(s) 6, 8, 21-37, 42 have been cancelled. Claim(s) 1-5, 7, 9-20, 38-41 are pending. Claim(s) 1 has been amended. Claim(s) 1-5, 7, 9-20, 38-41 are examined herein.

The terminal disclaimer filed on 10/17/2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent Application 10/288,761 and US Patent 6,753,325 has been reviewed and is accepted. The terminal disclaimer has been recorded. The obviousness double patenting rejections are hereby withdrawn.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9-20, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), Ishida (US Patent 5,141,741, of record), Nguyen (US Patent 5,650,137, of record), Bissett (US 6,051,602, PTO-892), Weiss (PTO 1449, of record), Kim (US Patent 5,776,460, of record), Darr (PTO 1449, of record), Shimoi (PTO 1449, of record) in view of "A Fact Sheet on the Health Effects from Ionizing Radiation" (EPA 402-F-98-010, of record)

Kita discloses that vitamin D including vitamin D3 (cholecalciferol), is useful in a dermatological composition for the protection and treatment of the skin and scalp from harmful UV radiation (see 6,162,801, abstract, col. 1, lines 22-24 and 51-67, col. 4, lines 13-16, and col. 8, lines 51 to col. 9). Kita also clearly teach that therapeutic vitamin D can be orally administered (col. 1, lines 42-44).

Ishida et al. discloses that alpha-lipoic acid and vitamin A, B, C, D, E, F, K, P, U are known to be useful in the protection of UV radiation or anti-sunburn in human skin. See abstract, col.5 lines 65-68. Thickeners may be added such as methyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose, carboxyvinyl polymers and the like (col. 5, lines 45-53).

Nguyen et al. discloses that superoxide dismutase or the porphyrins such as chlorophyllin, alone or in combination are antioxidants and have protective effects to human skin including against UV radiation. Example 3 contains crosslinked polyacrylic acid (Carbopol 940). See abstract, col. 1, col. 2, lines 20-31, col.3 lines 40-66, claims 1-11.

It is well settled in patent law that the selection of a known material based on its suitability for its intended use is *prima facie* obvious. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). What's more, the *prima facie* obviousness is also supported by the holding that homologs are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Bissett (US 6,051,602) discloses that the instant one or more flavonoids (also known as polyphenols and are known to be obtained from green teas extracts, including, quercetrin, catechin, epicatechin, and rutin compounds) are useful in a method of reduction or treatment skin conditions in human resulted from environmental damage or extrinsic factors such as UV radiation, pollution, wind, heat or IR, low humidity, harsh surfactants, by topically applying a composition comprising one or more flavonoids, a pharmaceutically acceptable carrier broadly (e.g., PPG), and other active agents such as anti-inflammatory agents and anti-oxidants such as vitamin A (retinol or retinyl derivatives) and C (ascorbic acid), with conventional skin care product additives such as kernel oil, panthenol, to human skin. See in Bissett, the abstract, col. 1, col. 2, lines 14-48, col. 3, lines 13-36 and 53-55, col. 4, lines 13-16, col. 4, lines 65 to col. 5,

line 49, col. 6, lines1-55, col. 7, lines 1-10, Example 1 and 3 at col. 9-10, and claims 1-11. Bissett discloses the effective amounts of one or more flavonoid compounds, about 0.01-20%, more preferably, about 0.1-10%, and most preferably about 0.5-5%, within the instant claim (see col. 5, lines 60-64).

Weiss et al. teach that antioxidants, such as vitamin E, selenium, and superoxide dismutase provide radioprotection, particularly injury due to ionizing radiation (abstract).

Kim et al. discloses that ginseng is known to be useful in the protection of radiation injury. See col. 1, lines 21-27.

Darr et al. discloses that vitamin C such as ascorbic acid or vitamin E is useful in a composition to be administered orally or topically in the treatment of the protection of UV radiation-induced damage. See Summary and page 247.

Shimoi et al. discloses that flavonoid / flavonoid derivatives from plant or tea are antioxidants and have radioprotective effects. See abstract.

The prior art does not expressly disclose the employment of a combination of vitamin D3, antioxidants, flavonoid / flavonoid derivatives, selenium, and ginseng in a composition to be administered in a method for the treatment or reduction of radiation injury to a human prior to expected exposure to radiation, where the radiation is selected from the group consisting of proton, fluoroscopic, alpha, beta, and gamma radiation.

The US Environmental Protection Agency discloses that ionizing radiation of primary concern are alpha, beta, gamma, and x rays, which can originate from natural sources or can be technologically produced. Natural radiation comes from cosmic rays,

naturally occurring radioactive elements found in the earth's crust, and radioactive decay products such as radon and its subsequent decay products. The latter group represents the majority of the radiation exposure of the general public. Technologically produced radiation can come from hospitals, research institutions, nuclear reactors, nuclear weapon facilities, and certain manufacturing processes (pg. 1, figure 1 of the Fact Sheet on the Health Effects from Ionizing Radiation, EPA 402-F-98-010, of record).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the combination of vitamin D3, antioxidants, flavonoid / flavonoid derivatives, selenium, and ginseng in a composition to be orally administered in a method for the treatment or reduction of radiation injury to a human prior to expected exposure to radiation, where the radiation is selected from the group consisting of proton, fluoroscopic, alpha, beta, and gamma radiation.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the combination of vitamin D3, antioxidants, flavonoid / flavonoid derivatives, selenium, and ginseng in a composition to be orally administered in a method for the treatment or reduction of radiation injury to a human prior to expected exposure to radiation, where the radiation is selected from the group consisting of proton, fluoroscopic, alpha, beta, and gamma radiation because: (1) each of the aforementioned components have been taught to be used for radioprotection. Vitamin D3 is known to be useful for the protection and treatment of harmful UV radiation. Antioxidants such as vitamin C (ascorbic acid) are known to be useful in the treatment and the protection of UV radiation-induced damage. Vitamin E, selenium,

superoxide dismutase, and ginseng are taught to provide radioprotection as well as flavonoid and its derivatives; (2) Weiss et al. teach that antioxidants, such as vitamin E, selenium, and superoxide dismutase provide radioprotection, particularly injury due to ionizing radiation; and (3) US Environmental Protection Agency discloses that ionizing radiation of primary concern are alpha, beta, gamma, and x rays, which can originate from natural sources or can be technologically produced. Therefore, one of ordinary skill in the art would have had a reasonable expectation to provide or improve the therapeutic effect in preventing injury as a result of proton, fluoroscopic, alpha, beta, and gamma radiation by combining vitamin D3, antioxidants, flavonoid / flavonoid derivatives, selenium, and ginseng in an oral composition administered to a human before exposure to proton, fluoroscopic, alpha, beta, and gamma radiation.

Further, flavonoid and its derivatives and ginseng are known antioxidants and also known to be useful in the protection of radiation injury. Therefore, one of ordinary skill in the art would have reasonably expected that further adding flavonoid and its derivatives and ginseng to the composition herein known useful for the same purpose, in a composition to be administered would provide additive effects for the therapeutic treatment in radiation injury.

Since all active composition components herein are known to useful to treat radiation injury, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Examiner views that the patient population is inherent because of the overlap between people in need of radioprotection resulting from proton, fluoroscopic, alpha, beta, and gamma radiation and those people in need of radioprotection from UV radiation. In order for people to enter or leave facilities such as hospitals, research institutions, nuclear reactors, nuclear weapon facilities, and certain manufacturing processes, where they are at risk for radiation injury resulting from proton, fluoroscopic, alpha, beta, and gamma radiation, they must first come in from outside or leave the building, where they are in need of UV protection. Therefore, anyone and everyone is in need of UV protection, especially since they will be exposed to powerful UV radiation by going outside or any place indoor where they are exposed to sunlight. Similarly, it is same people who need protection from UV radiation that also need protection from other radiation sources such as radon, which can be found in water supplies, mines, and household basements.

Furthermore, one of ordinary skill in the art would have reasonably expected that the combination herein would have the same or substantially the same beneficial therapeutic effects in proton, fluoroscopic, alpha, beta, or gamma radiation, as in UV radiation-induced damage.

Examiner also views that oral and topical administration are well known methods of administration that can be interchanged depending on disorder, bioavailability, and patient compliance. Vitamins, flavonoids, ginseng, tea extracts, and antioxidants are well known in the art to be orally administered. For example, Darr et al. discloses that vitamin C such as ascorbic acid or vitamin E is useful in a composition to be administered orally or topically in the treatment of the protection of UV radiation-induced damage. Kita also clearly teach that therapeutic vitamin D can be orally administered (col. 1, lines 42-44). Unless, Applicant shows the criticality of one form of administration over the others, it is obvious to formulate a composition to be orally administered.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER